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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/852,182	05/09/2001	John P. Hamman	Nut-0003	4884
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Gary J. Calton 5331 Landing Road Elkridge, MD 21075			EXAMINER ROBERTS, LEZAH	
			ART UNIT 1614	PAPER NUMBER
			MAIL DATE 10/18/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

09/852,182

Applicant(s)

HAMMAN ET AL.

Examiner

Lezah W. Roberts

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 01 August 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 37-56 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 37-56 is/are rejected.
- 7) ☒ Claim(s) 37-56 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

This Office Action is in response to the Request for Continued Examination filed August 1, 2007. All previous rejections have been withdrawn unless stated below.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Status: The status of the claims labeled Currently Amended is incorrect. The claims should be listed as New Claims because they were not presented before under the recited claim numbers.

The claims will be considered New Claims.

### ***Claims***

#### **Claim Objections**

Claims 37-56 are objected to because of the following informalities: the claims recite "based upon the weight of the amino acid component". This limitation is redundant because the limitation is set forth at the end of claim 47 with regards to the weight of the amino acid component. Appropriate correction is required.

#### **Claim Rejections - 35 USC § 112 – Written Description (New Rejection)**

Claims 41, 44-46, 51 and 54-56 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to

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reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims recite the phrases "hydroxy analogs", "keto analogs" and "protein hydrolysates" but do not give a representative set of each of these compounds to support the general recitation of "hydroxy analogs", "keto analogs" and "protein hydrolysates".

The appearance of mere indistinct words in a specification or a claim (here the compounds "hydroxy analogs", "keto analogs" and "protein hydrolysates"), even an original claim, does not necessarily satisfy the written description requirement. The disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter purportedly described. Univ. of Rochester v. G.D. Searle, 69 USPQ2d 1886, 1892 (CAFC 2004). In regards to hydroxy analogs and keto analogs, the specification only discloses compounds such as L-alanine, L-aspartic acid, L-citrulline, L-cystine, L-glutamic acid, L-glutamine, L-histidine, L-isoleucine, L-leucine, L-lysine, L-methionine, D,L-methionine L-omithine, L-phenylalanine, L-proline, L-serine, L-threonine, L-tryptophan, L-tyrosine, L-valine, where the amino acids have the amine group replaced with a keto or hydroxyl group, respectively. These include creatine, carnitine and mixtures thereof. In regards to protein hydrolysates, the specification only discloses hydrolyzed egg albumin or hydrolyzed whey, either fully or partially hydrolyzed. The specification does not disclose other possible structures for hydroxy or keto analogs or when a compound is no longer an analog of the disclosed amino acids. In regards to the hydrolysates, the specification does not disclose other types of hydrolysates that are encompassed by the broad description of protein hydrolysates.

**Claim Rejections - 35 USC § 102 – Anticipation (Previous Rejection)**

Claims 1-5, 8-9, 11-23, 26-27 and 29-36 were rejected under 35 U.S.C. 102(e) as being anticipated by Ojima et al. (US 7,029,717). The rejection is maintained and applied to new claims 37-40, 43-50 and 53-56.

**Applicant's Arguments**

Applicant has amended the claims to set forth the limitation that the sucralose components weight is based on the amount of amino acid or protein hydrolysate present. Applicant argues that the amount of sucralose used in the reference exceeds the amounts used in the invention of the instant claims. Applicant makes reference to several Examples in the reference to show that the amounts of sucralose are different than those instantly claimed. Applicant further points out "that the addition of the amino acids, or protein hydrolysates are not for the purpose of taste masking, but for achieving the "sweetness-improving effect"". This argument is not persuasive.

**Examiner's Response**

The reference discloses, as pointed out by Applicant, an example wherein the sucralose to protein hydrolysate is in a ratio of 1:5. This roughly calculates to about 16.6%. The instant claims uses the language "about", which may include percentages of more than 15% or less than 15%. This includes about 16.6%. The term "about" permits some tolerance. See, for example, In re Ayers, 69 USPQ 109 (CCPA 1946), where "at least about 10%" was held to be anticipated by a teaching of a content "not to exceed about 8%." Furthermore the amount of sucralose in the case of the 1:5 ratio would also

be dependent on the total amount of the composition. Therefore this ratio may encompass percentages lower than 16.6%. The reference teaches not less than 0.0001 parts by weight, this is the lower limit, not the higher limit. Therefore the compositions encompass the instant claims. The Examiner reminds Applicant that the instant claims not only recite a method for taste masking but also a composition, therefore the intended use of the composition or its components carries no weight in determining patentability. This is because the compositions of the reference, comprising sucralose and a protein hydrolysate or amino acid, are substantially the same as the compositions of the instant claims. That being said the sucralose should be able to mask the taste of the protein hydrolysate or amino acid because the composition of the reference and the compositions of the instant claims are substantially the same. Although the reference does not disclose the sucralose as a taste masker, it is used as a sweetener and therefore will mask bitter taste because it sweetens the compositions no matter what the other components are in it.

**Claim Rejections - 35 USC § 102 – Anticipation (New Rejection)**

Claims 44-46 and 54-56 are rejected under 35 U.S.C. 102(e) as being anticipated by Liu et al. (US 6,773,730).

Liu et al. disclose chewing gum compositions comprising hydrolyzed zein. The Zein comprises 20% to 65% by weight of the gum base (col. 2, lines 16-18). The gum base comprises 10 to 95% of the gum. Therefore the zein will comprise from 2% to 61.8% of the chewing gum. Sweeteners such as sucralose are added to the gum base

and comprise 0.1% to 0.3% by weight of the gum. Therefore sucralose may comprise from 0.16% to 13% by weight of the zein hydrolysate when taking in consideration the hydrolysate and sucralose together as a sub-composition. The compositions also comprise a bitterness taste-masking agent (col. 6, lines 62 to col. 7, line 8), therefore the compositions encompass the instant claims. The reference anticipates the claims insofar as it discloses a composition comprising sucralose and a protein hydrolysate.

**Claim Rejections - 35 USC § 103 – Obviousness (Previous Rejection)**

Claims 7, 10, 25 and 28 were rejected under 35 U.S.C. 103(a) as being unpatentable over Ojima et al. (US 7,029,717) in view of Newsholme et al. (US 5,639,731). The rejection is maintained and applied to claims 42 and 52.

**Applicant's Arguments**

See Applicant's arguments above. Applicant discusses in detail the ratios of using the lower limits discussed in the reference to show the sucralose is used in excess as compared to the compositions of the instant claims. Applicant states "There is no particular limitation on the upper limit from the standpoint of insuring the effect of the invention, although the taste of said defined substance to be used, among other variables, should be taken into consideration." This supports that the amino acid is a minor ingredient and may adversely affect the taste of the sucralose rather than the reverse as claimed by Applicant. Ojima et al. did not perceive the present invention. The amino acid would seem as an impurity, which might potentially have a bad taste on sucralose. In regards to Newsholme et al., if the two compositions were combined, the

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amount of sucralose present would surpass the solubility of sucralose in water. These arguments are not persuasive.

*Examiner's Response*

As discussed above the amount of amino acid or protein hydrolysate disclosed by the reference is the lower limit. The amount of amino acid or protein hydrolysate may exceed that of the sucralose as exemplified in Example 45. One would use the sucralose, which is a sweetener, to offset or mask the bitter taste of the compositions in the secondary reference by sweetening the compositions. It would also be reasonable for one of ordinary skill in the art to use sucralose in the compositions because the primary reference discloses that the combination of sucralose and amino acid has a "sweetness-improving effect", making it obvious to use a compound that can enhance the taste of the compositions by decreasing the bitter taste with a sweet taste.

**Conditional Request for Constructive Assistance**

Applicant has stated that the specification has been amended but there appears to be no submitted amendments of the specification.

Claims 37-56 are rejected.

Claims 37-56 are objected.

No claims allowed.



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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lezah W. Roberts whose telephone number is 571-272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Lezah Roberts  
Patent Examiner  
Art Unit 1614



Frederick Krass  
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